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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/514,626	06/23/2005	Finn Skou Pedersen	PEDERSEN10	7989

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/514,626	PEDERSEN ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6-19,21,22,24,27-33,35-40 and 42-48* is/are pending in the application.

4a) Of the above claim(s) *11-19,21,22,24,27-33 and 35-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6-10,47 and 48* is/are rejected.

7)☒ Claim(s) *9, 42-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 9/25/2008. Note that any rejections not reiterated have been withdrawn. The office apologizes for the confusion that the comments found in the margin may have caused. Applicant correctly stated what the rejections are (see page 16 of REMARKS, section 3.2).

Specification

The title has been changed to PURIFIED RETROVIRAL ENVELOPE POLYPEPTIDE as requested.

Claim Rejections - 35 USC § 112-NECESSITATED BY AMENDMENTS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to a specific 15 amino acid region of SEQ ID NO: 2 (amino acids 199-213) and there is no support in the specification which describes this specific region. Applicant is invited to point out where in the specification this region is disclosed.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6, 8 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Sijts et al as evidenced by Yang et al. See alignment in previous action.

Sijts et al clone the MCF1233 MLV and identify the sequences involved in viral tropism, oncogenicity and T cell epitope formation (see whole document). Figure 3 (page 346) provides a sequence alignment of the MCF1233 env protein with that of AKV, NCF247 and HOL. The sequence alignment that follows consists of the MCF1233 env protein sequence with the sequence set forth by SEQ ID NO: 2 of the instant application; analyses show a 94.6% homology between the two sequences with a glycine residue at the homologous site 212. Note that SEQ ID NO:2 contains an arginine at site 212. Claim 47 is met; see alignment provided in the previous action.

Yang et al provides supportive teachings that human cells are permissive to MCF virus (see page 217); also described are the polytropic and xenotropic receptors for mice. Thus, the limitations of 4, 6 and 8 are met by the prior art.

Response to Arguments

Applicant's arguments filed 9/25/2008 have been fully considered but they are not persuasive. Applicant amended the claims to so that they are drawn to sequences with 95% homology in contrast to the original 94%. Note that Sijts et al provide a sequence with 94.6% homology which may round up to 95% wherein the homologous site at 212 differs in amino acid. Further noted is that Sijts compares nucleotide sequences of viral relatives (MuLV, see Abstract). The substitutions or previously claimed mutations (see instant claim 6) meet those that are evolutionarily derived

leading to homologous viral relatives. Lastly, the claim is drawn to fragments and the taught sequence provides many fragments that are 95% similar to SEQ ID NO: 2. Thus, structurally, the limitations have been met. Functionally, Yang et al provide that human cells are permissive to MCF virus and this meets "capable of mediating infection of a human cell" (see claims 4 and 8). Yang et al provides which receptors are required by the cell for this mediation and Applicant acknowledges this on page 20 of REMARKS. It is further noted that "a chemical composition and its properties are inseparable" (see MPEP 211) and the teachings of Sijts meet the structural limitations so that the functional properties would be inherent. Note that the arguments are not clear. The claims are drawn to a product and not a method by which the product is developed.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., mutational analyses, Rmc1 locus) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 102/103-MAINTAINED

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 7 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sijts et al (1994).

The teachings of Sijts et al meet the structural limitations of the env protein in claim 4. However, it cannot be determined by examination whether the structure's tropism can be altered following one substitution or if the structure is capable of mediating a higher infectivity in human cells than other viruses, specifically, MCF-247, MCF-13 and X-MLV. While it is known to the ordinary artisan that there exists a correlation of structure to function of a protein, such that, a change in structure (i.e. a substitution) leads to a change in function, the Office has no laboratory to ascertain whether a change in function will lead to altered tropism. Further, the function of a protein is inherent to its structure. See MPEP 2112.

Response to Arguments

Applicant's arguments filed 9/25/2008 have been fully considered but they are not persuasive. No argument or no clear argument was provided.

Allowable Subject Matter

Claims 9, 42-46 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note that claim 48 is additionally rejected under 35 USC 112, 1st paragraph (New Matter).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is

(571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648